CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
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July 19, 2000

U.S. Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: **Improving Premarket Review and Approval of Food and Color Additives in the Center for Food Safety and Applied Nutrition; Request for Comments**
Docket Number 00N-1262
65 Fed.Reg. 26215 (May 5, 2000)

On behalf of its more than 700,000 American members, the Center for Science in the Public Interest ("CSPI") appreciates the opportunity to comment on how the Food and Drug Administration (FDA) can improve its premarket review process for food and color additive petitions. CSPI has had a longstanding interest in the agency's activities related to food and color additives. We have filed numerous citizen petitions and comments seeking FDA action on additives that we believed were unsafe or inadequately tested.

CSPI applauds the agency for seeking public input on how its new resources should be used to address the public-health issues related to food and color additives. The influx of new resources offers FDA an excellent opportunity to take several immediate steps to improve the Office of Premarket Approval.

FDA Should Change the Name of the Office of Premarket Approval to the "Office of Food Chemical Review"

CSPI's first suggestion would cost FDA little or no money. The Office of Premarket Approval, which is responsible for *reviewing* -- without necessarily approving -- the safety of proposed food and color additives, should be renamed the "Office of Food Chemical Review." That would eliminate any perception that approval of additives is preordained. It would also make it plain that the food and color additives under review are "chemicals" and that the safety review includes an examination of data from toxicological and other tests appropriate to chemical additives. Though largely symbolic, the name change would help assure the public that the office understands its primary role to be safeguarding consumers from unsafe chemical additives.

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FDA Should Continue to Give High Priority to Reviewing Antimicrobial Additives and Should Also Expedite Review of Additives That Make Food More Nutritious

CSPI strongly supported FDA's decision in early 1999 to expedite review of food additives with antimicrobial properties against human pathogens, and we believe that that policy should remain in effect. Helping to eliminate foodborne illness caused by microbial contamination is a particularly important and laudable function for food additives.

Though review of food additives that enhance food safety should remain FDA's highest priority, new additives that make food more nutritious should also be reviewed ahead of additives that offer little or no health benefits. Therefore, FDA should review additives that increase the nutritional value of foods more expeditiously than additives offering no nutritional or food-safety benefits.

Of course, the agency would have to establish criteria for determining whether an additive actually improves the nutritional quality of food. That task should be relatively straightforward. We suggest that FDA consider such factors as whether the additive would facilitate the production of foods containing higher levels of fiber or micronutrients or less fat (especially saturated and *trans* fats), added sugars, or sodium, and whether the additive would encourage the consumption of healthy foods that many Americans do not include in their diets.

FDA Should Invest More Heavily in Ensuring the Safety of Approved Additives

CSPI has been disappointed by the low priority FDA places on addressing lingering safety questions posed by additives (or GRAS substances) that have already been approved by the agency. FDA should use some of its new funding to re-evaluate the safety of approved additives that have raised safety concerns.

A simple, relatively inexpensive step that FDA could take immediately would be to devote additional staff time to conducting reviews of the scientific literature related to food-additive safety. That review should be comprehensive and ongoing, and there should be a system in place to get relevant information from the literature about unsafe additives to the appropriate agency personnel without delay.

FDA should also devote some its resources to improving its post-market surveillance for adverse reactions to food and color additives. Admittedly, conducting such surveillance effectively is a challenging task, because tracing an adverse reaction to a particular additive in a person's diet obviously can be quite difficult. However, FDA should explore new ways to increase health-care providers' awareness that additives can cause gastrointestinal symptoms, allergic reactions, and other health problems. It should also develop new mechanisms to encourage health-care providers to ask patients suffering from such symptoms questions about their use of food-additive-containing products and to report adverse reactions to the agency.

Because animal and *in vitro* toxicity and allergenicity tests offer only limited insight into how food and color additives may affect consumers, post-market surveillance could play a

critical role in the detection of unsafe additives. Accordingly, FDA should use some of its new resources to develop and test new ways to conduct post-market surveillance. We note that improving adverse event reporting (AER) is among the agency's stated goals under the FY 2001 Performance Plan, but that this effort is to be focused on dietary supplements and other special nutritional products.[1] We urge FDA also to increase its efforts to monitor and evaluate adverse events due to food and color additives (and GRAS substances) as part of its AER activities.

When post-market surveillance, literature reviews, or other information indicates that an approved additive may be unsafe, FDA should ensure that follow-up research is conducted to ascertain the extent of the problem and to determine an appropriate regulatory response. FDA should either undertake that research itself or require the company marketing the potentially unsafe additive to do so.

In addition, FDA should devote additional resources to responding more quickly to citizen petitions seeking agency action to address potentially unsafe additives. CSPI's petitions have tended to languish. For example, FDA has yet to respond to our 1997 petition requesting the agency to conduct a safety review of caffeine and require appropriate labeling, our 1998 petition seeking a complete ingredient listing or prohibition on the use of cochineal extract and carmine color additives, or our 1999 petition calling for a ban on potassium bromate in baked goods. While companies and industry trade associations have been vociferous critics of the length of time it takes FDA to approve new food additive petitions, the sluggish pace of citizen-petition review is the unaddressed flip side of the coin. In this regard, we note that FDA has included as a goal under its FY 2001 Performance Plan reducing the percentage of overdue food and color additive petitions, but the agency has no similar goal regarding citizen petitions related to food additives.[2] That should change. In terms of public health, responding to concerns about risks should take precedence over approving most food additives.

FDA Should Fund or Conduct New Research on Potential Safety Problems Posed By Additives

FDA should use some of its new resources to fund research to shed light on potential safety problems posed by new food and color additives. The agency has an important role to play in fostering the development of improved safety tests for chemical additives and for incorporating the latest science into its review process. Among other research activities, FDA should fund or conduct studies aimed at the following:

- Developing more sensitive animal and *in vitro* methodologies to test for carcinogenicity and toxicity;

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[1] Food and Drug Administration, *FDA FY 2001 Performance Plan*, p. 9, available at <http://www.fda.gov/ope/fy01plan/foods01.html>Internet [hereinafter cited as *FY 2001 Performance Plan*].

[2] *FY 2001 Performance Plan*, pp. 6-7.

- Developing tests to assess food sensitivities and allergenicity;[3] and
- Investigating links between diet and Attention Deficit/Hyperactivity Disorder (ADHD).

FDA Should Improve its Policies Regarding Advisory Committees

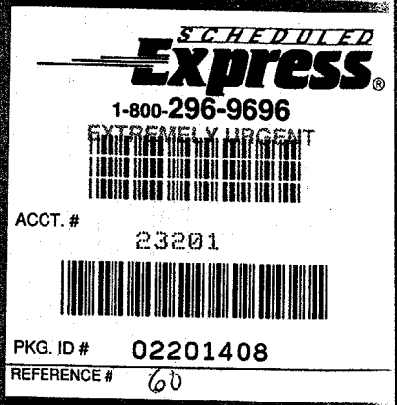
The Office of Premarket Approval should ensure that any advisory committees convened to review the safety of proposed (or existing) additives are balanced, have access to all appropriate information, and that members have adequate opportunity to review the data. As we have noted in the past, the committee that reviewed olestra was heavily skewed toward industry consultants. Moreover, the FDA failed to appoint any members on carotenoids, despite having discussed that matter with CSPI staff prior to the meeting. Having a balanced committee with expertise in the key relevant areas would not only help the FDA come to the best decision, but it would also enhance the credibility of the process. In addition, the FDA should provide full information to the public about possible biases and conflicts of interest of committee members, along the lines that the National Research Council does for some of its committees.

Thank you for the opportunity to provide this input.

Sincerely,

Michael F. Jacobson, Ph.D.
Executive Director

[3] For instance, monosodium glutamate sensitivity has been a lingering controversy that could be easily settled by appropriate tests. FDA should ensure that those tests are done.



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